IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA

Richmond Division

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| WILLIE CLAUDE PORTER,<br>Plaintiff,<br><br>v.<br><br>DEPUY ORTHOPAEDICS, INC.,<br>Defendant. | ) | Civil No. 3:19cv007 (REP) |

REPORT AND RECOMMENDATION

Plaintiff Willie Claude Porter ("Plaintiff") brings this action against Defendant DePuy Orthopaedics, Inc. ("DePuy"),[1] alleging that DePuy committed gross and ordinary negligence, breached express and implied warranties, and should be held strictly liable for design defects related to a knee replacement device installed in Plaintiff's left knee. This matter comes before the Court for a Report and Recommendation pursuant to 28 U.S.C. § 636(b)(1)(B) on DePuy's Motion to Dismiss (ECF No. 18), moving pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss all counts of Plaintiff's Complaint for failure to state a claim upon which relief can be granted. For the reasons set forth below, the Court recommends that DePuy's Motion to Dismiss (ECF No. 18) be GRANTED, that Counts I, II, III and VII of Plaintiff's Complaint (ECF No. 1)

[1] DePuy Orthpaedics, Inc. now operates as Medical Device Business Services, Inc. (Def.'s Br. in Supp. of its Mot. to Dismiss Pl.'s Compl. ("Def.'s Mem.") (ECF No. 19) at 1 n.1.) Because no party has moved to substitute Medical Device Business Services, Inc. as the new interested party in this case, the Court will continue to refer to DePuy by its old name. *See* Fed. R. Civ. P. 25(c) (stating that when an interest in a lawsuit is transferred to a new party, the lawsuit "may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party").

be DISMISSED WITHOUT PREJUDICE and that Counts IV, V and VI be DISMISSED WITH PREJUDICE.

## I. BACKGROUND

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts Plaintiff's well-pleaded factual allegations as true, though the Court need not accept Plaintiff's legal conclusions. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Based on this standard, the Court accepts the following facts.

### A. DePuy's Rotating Platform Knee Implant

DePuy manufactures, markets and distributes several knee replacement implants, including fixed bearing knees, rotating platform knees and high flexion knees. (Compl. (ECF No. 1) ¶¶ 15-16.) Relevant here, DePuy pioneered a rotating platform knee ("RPK") implant to mirror the natural movements of a patient's original knee with structural bearings that can rotate. (Compl. ¶¶ 17, 20.) Indeed, DePuy advertised that its RPK implants provided more natural movement, involved less wear on the implants' parts and permitted rotation. (Compl. ¶ 19.) DePuy also held itself out "as [a] global leader[] in hip, knee and shoulder replacement, and as the largest provider of orthopaedic and neurological solutions in the world." (Compl. ¶ 21.)

Before 2012, however, DePuy became aware that its knee replacement implants, including its RPK implants, often failed prematurely, causing patients extreme pain and tissue and bone damage. (Compl. ¶ 22.) Specifically, although an unidentified party, presumably DePuy, advertised that DePuy's knee implant systems could last approximately fifteen years, several reports found that a considerable number of DePuy's implants failed after only one or two years. (Compl. ¶ 24.) In fact, in the last several years, DePuy has issued multiple recalls for components of its knee replacement systems. (Compl. ¶ 26.)

**B. Plaintiff's Knee Replacement**

On September 12, 2012, Plaintiff underwent a total left knee replacement surgery, during which Plaintiff's surgeon installed DePuy's RPK implant. (Compl. ¶ 27.) Approximately one year later, in late 2013, Plaintiff began complaining about sudden pain and swelling in his left knee. (Compl. ¶ 28.) Plaintiff's treating physician referred Plaintiff to physical therapy and ordered x-rays of his left knee. (Compl. ¶ 29.) Plaintiff's x-rays revealed no evidence of loosening in Plaintiff's RPK implant at that time; however, Plaintiff's physician observed some swelling. (Compl. ¶ 29.) Plaintiff attended physical therapy for several weeks thereafter. (Compl. ¶ 30.)

Between 2014 and 2016, despite attending physical therapy and receiving cortisone shots, Plaintiff continued to experience worsening pain, swelling, stiffness and weakness in his left knee. (Compl. ¶¶ 31-33.) In January 2017, Plaintiff started treatment with a new orthopedic physician, who ordered additional x-rays and scans of Plaintiff's left knee. (Compl. ¶¶ 33-35.) Upon review of the additional imaging, Plaintiff's new orthopedist identified knee replacement failure as a potential cause of Plaintiff's continued knee problems. (Compl. ¶¶ 35-37.) Specifically, Plaintiff's orthopedist noted possible loosening of the RPK implant. (Compl. ¶ 37.)

Between February and July 2017, Plaintiff underwent nonsurgical treatments for his left-knee pain that proved ineffective. (Compl. ¶ 38.) Consequently, on August 29, 2017, Plaintiff underwent a total knee revision surgery. (Compl. ¶ 39.) At the time of Plaintiff's revision surgery, Plaintiff's surgeon noted pain, swelling and effusion in Plaintiff's left knee, "with documented infection." (Compl. ¶ 39 (internal quotations omitted).) Plaintiff's surgeon also noted "aseptic loosening of the femoral and tibial components" of Plaintiff's RPK implant. (Compl. ¶ 39 (internal quotations omitted).) The revision surgery caused pain, permanent

impairment and weakness in the ligaments, bone and muscles surrounding Plaintiff's left knee. (Compl. ¶¶ 41-42.) Plaintiff may also require additional revision surgeries in the future. (Compl. ¶ 43.)

**C. Plaintiff's Complaint**

On January 7, 2019, Plaintiff filed suit in this Court against DePuy, several DePuy affiliates and companies associated with Johnson & Johnson. (ECF No. 1.) On May 7, 2019, Plaintiff filed a stipulation of voluntary dismissal, dismissing without prejudice all defendants except DePuy. (Stipulation of Voluntary Dismissal Without Prejudice (ECF No. 17) at 1.)

Based on the above facts, Plaintiff's Complaint raises seven counts for relief. In Count I, Plaintiff alleges that DePuy breached its duty to use reasonable care in the manufacture, sale and distribution of its RPK implants. (Compl. ¶¶ 46-52.) Specifically, Plaintiff alleges that DePuy committed wanton, reckless, grossly negligent and negligent acts by: (1) manufacturing, inspecting, marketing, distributing, selling and supplying the RPK implants "in such a way that persons using the product would be subject to unreasonable danger;" (2) failing to warn hospitals and patients that the RPK implants performed defectively; (3) placing or permitting the placement of the RPK implants into the stream of commerce when DePuy knew or should have known that the implants performed defectively; (4) failing to limit the harm caused by the RPK implants; (5) manufacturing, inspecting, marketing, distributing, selling and supplying the RPK implants in an unsafe condition; (6) failing to maintain awareness of and respond to public, governmental and industry studies, reports, information, recommendations and complaints regarding problems with the RPK implants; and, (7) failing to exercise due care under the circumstances. (Compl. ¶ 51(A)-(H).)

In Count II, Plaintiff alleges that DePuy breached the express warranties made through the advertisement, marketing and promotion of its RPK implants, which represented the implants as safe, effective and appropriate for their intended use. (Compl. ¶¶ 53-59.) In Counts III and IV, Plaintiff alleges that DePuy breached the implied warranties of merchantability and fitness for a particular purpose. (Compl. ¶¶ 60-73.)

In Count V, Plaintiff alleges that the design defects in the RPK implants render DePuy strictly liable. (Compl. ¶ 76-82.) Similarly, in Count VI, Plaintiff alleges that DePuy should be strictly liable, because the RPK implants failed to conform to DePuy's representations and caused serious physical injury to Plaintiff. (Compl. ¶¶ 83-87.) For both Counts V and VI, Plaintiff asserts that DePuy's conduct warrants the imposition of punitive damages. (Compl. ¶¶ 82, 87.)

Finally, in Count VII, Plaintiff alleges that DePuy's conduct represented a willful and wanton disregard for the rights of others such that Plaintiff has a right to punitive damages at common law. (Compl. ¶¶ 88-94.) Based on these seven counts, Plaintiff seeks $1,000,000.00 in compensatory damages, $350,000.00 in punitive damages, pre- and post-judgment interest and any other relief that the Court deems proper. (Compl. at 17-18.)

**D. DePuy's Motion to Dismiss**

On May 8, 2019, DePuy filed its Motion to Dismiss (ECF No. 18), moving this Court pursuant to Rule 12(b)(6) to dismiss all counts of Plaintiff's Complaint. In support of its Motion, DePuy argues that federal law preempts Plaintiff's claims, citing to the Supreme Court's holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323-24 (2008), for the proposition that the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360c *et seq.*, expressly preempts state common-law claims that impose different or additional requirements on device manufacturers.

(Def.'s Mem. at 7-12.) DePuy points to other federal court decisions relying on the preemption doctrine to dismiss similar state-law claims related to the exact same knee implant at issue here. (Def.'s Mem. at 9-12 (citations omitted).)

Even if federal law does not preempt Plaintiff's claims, DePuy contends that Plaintiff has nonetheless failed to state claims upon which relief can be granted. For one, DePuy maintains that Plaintiff's strict liability claims (Counts V and VI) must fail, because they improperly allege strict liability under Ohio law when none of Plaintiff's allegations render Ohio law applicable. (Def.'s Mem. at 14.) Instead, DePuy argues that Virginia law, which provides no strict liability scheme for product defects, applies to Plaintiff's claims. (Def.'s Mem. at 14.)

As for Plaintiff's negligence claim in Count I, DePuy contends that Plaintiff has failed to identify any specific defect in the RPK implant that caused his alleged injuries. (Def.'s Mem. at 15.) DePuy adds that Plaintiff has also failed to identify how a different implant design or manufacturing process would have prevented his alleged injuries. (Def.'s Mem. at 15.) DePuy asserts that Plaintiff's warranty claims (Counts II, III and IV) likewise prove implausible, because Plaintiff alleges no specific facts to support those claims. (Def.'s Mem. at 15-17.) And DePuy argues that the Court should dismiss Count VII, because Virginia law does not recognize a standalone cause of action for punitive damages. (Def.'s Mem. at 17.) Finally, anticipating Plaintiff's argument that the Court should permit further discovery of his claims, DePuy maintains that the plausibility standard exists to prevent discovery of anemic claims, even when information necessary to a claim lies exclusively within a defendant's possession. (Def.'s Mem. at 17-18 (citations omitted).)

On May 23, 2019, Plaintiff filed his Response to DePuy's Motion to Dismiss, (Pl.'s Resp. to Def.'s Mot. to Dismiss ("Pl.'s Mem.") (ECF No. 22)), and DePuy filed its Reply on May 28,

2019, (Reply Br. in Supp. of Def.'s Mot. to Dismiss Pl.'s Compl. ("Def.'s Reply") (ECF No. 25)), rendering the matter now ripe for review.

## II. STANDARD OF REVIEW

A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of a complaint or counterclaim; it does not serve as the means by which a court will resolve contests surrounding the facts, determine the merits of a claim or address potential defenses. *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). In considering a motion to dismiss, the Court will accept a plaintiff's well-pleaded allegations as true and view the facts in a light most favorable to the plaintiff. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678.

Under the Federal Rules of Civil Procedure, a complaint or counterclaim must state facts sufficient to "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests[.]'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). As the Supreme Court opined in *Twombly*, a complaint or counterclaim must state "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action," though the law does not require "detailed factual allegations." *Id.* (citations omitted). Ultimately, the "[f]actual allegations must be enough to raise a right to relief above the speculative level," rendering the right "plausible on its face" rather than merely "conceivable." *Id.* at 555, 570. Thus, a complaint or counterclaim must assert facts that are more than "merely consistent with" the other party's liability. *Id.* at 557. And the facts alleged must be sufficient to "state all the elements of [any] claim[s]." *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761,

765 (4th Cir. 2003) (citing *Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) and *Iodice v. United States*, 289 F.3d 270, 281 (4th Cir. 2002)).

## III. CHOICE OF LAW

As a threshold matter, the Court must determine the substantive law against which to measure the plausibility of Plaintiff's claims. Because Plaintiff's claims fall under state law, this Court, sitting in diversity, must apply the substantive law of the state in which it sits, including its choice-of-law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496-97 (1941).

In Virginia, "the place of the wrong (*lex loci delicti*) determines which State's substantive law" governs actions that sound in tort. *Quillen v. Int'l Playtex, Inc.*, 789 F.2d 1041, 1044 (4th Cir. 1986) (emphasis supplied) (citing *McMillan v. McMillan*, 253 S.E.2d 662, 663 (Va. 1979)). Thus, Virginia law governs Counts I, V, VI and VII of Plaintiff's Complaint, because all four counts rely on either a negligence, gross negligence, willful and wanton conduct or strict liability theory, which sound in tort, and Plaintiff underwent his knee replacement surgery in Virginia. *See Williams v. Gyrus ACMI, Inc.*, 790 F. Supp. 2d 410, 415 (D. Md. 2011) (holding under Maryland's identical *lex loci delicti* principle that the place of the wrong for a defective medical implant is the place where surgeons first installed the implant in a patient's body, "because the patient can immediately bring suit for the object's removal" (collecting cases)); (Compl. ¶ 13 (averring that Plaintiff underwent knee replacement surgery in Virginia and first experienced problems with his implant in Virginia); *see also McMillan*, 253 S.E.2d at 663 (characterizing negligence as a tort for choice-of-law purposes); *M.W. Worley Const. Co. v. Hungerford, Inc.*, 210 S.E.2d 161, 163-64 (Va. 1974) (implicitly characterizing strict liability as a tort action). Because Virginia law governs Plaintiff's strict liability claims, those claims must fail, for the Virginia Supreme Court has not adopted a strict liability scheme in products liability cases. *See*

*Lust v. Clark Equip. Co.*, 792 F.2d 436, 439 (4th Cir. 1986) (noting that Virginia has not adopted a general strict liability cause of action); *Worley*, 210 S.E.2d at 163-64 (adopting strict liability scheme only in cases involving "an intrinsically dangerous and ultrahazardous activity," such as blasting); (*see also* Pl.'s Mem. at 1 (conceding that Plaintiff included his strict liability claims in error).) Accordingly, the Court recommends that Counts V and VI be dismissed.

Virginia law also governs Plaintiff's warranty claims (Counts II, III and IV). In Virginia, express and implied warranties in the sale of a good fall under Virginia's Uniform Commercial Code ("UCC"). Va. Code §§ 8.2-313-8.2-315. Virginia's UCC provides that unless a transaction "bears a reasonable relation to [Virginia] and also to another state or nation" and the parties "agree that the law of either [Virginia] or such other state or nation shall govern their rights and duties," the "rights and obligations of the parties are determined by the law that would be selected by application of [Virginia's] conflict of laws principles." Va. Code § 8.1A-301(b)-(c). Here, the parties did not agree that the law of another reasonably related state or nation should govern; thus, Virginia's conflict of laws principles will determine the substantive law to be applied.

To that end, the Virginia Supreme Court has characterized breach of warranty claims at common law as sounding in tort. *See E.I. Du Pont De Nemours & Co. v. Univ. Moulded Prods. Corp.*, 62 S.E.2d 233, 236 (Va. 1950) ("[A] complainant may, . . . where there is a breach of warranty, . . . sue in tort." (internal quotations and citations omitted)). Indeed, Virginia law does not require privity between a reasonably foreseeable user and the manufacturer of an allegedly defective good to sustain a products liability action. Va. Code § 8.2-318; *Hamlett v. Va. Vascular Assocs.*, 61 Va. Cir. 468, 470 (2003); *see also Pulte Home Corp. v. Parex, Inc.*, 579 S.E.2d 188, 191 (Va. 2003) (noting that privity becomes a requirement for breach of an implied

warranty if, unlike the cause of action here, the action seeks consequential economic losses). However, the warranty provisions in Virginia's UCC presuppose the existence of a contract for the sale of goods, suggesting that such claims sound in contract. *See* Va. Code § 8.2-313-8.2-315 (providing for implied and express warranties that form part of the contract or the "basis of the bargain" between the parties). In any case, because Virginia follows the traditional rule that "questions of substantive law are governed by the law of the place of the transaction or the place where the right is acquired," whether Plaintiff's warranty claims sound in tort or contract proves inconsequential, for Plaintiff's purchase of the RPK implant and his alleged damages both occurred in Virginia, meaning Virginia law governs under either a tort or contract theory. *Frye v. Commonwealth*, 345 S.E.2d 267, 272 (Va. 1986); (Compl. ¶ 13.)

## IV. ANALYSIS

As mentioned, DePuy primarily argues that the MDA preempts all five remaining Counts of Plaintiff's Complaint. However, because the question of preemption requires the Court to consider the nature, form and plausibility of Plaintiff's claims under state law, the Court will consider in turn both the plausibility of Plaintiff's claims under state law and their potential preemption. For the purposes of its analysis, the Court takes judicial notice that the RPK implant at issue in this suit constitutes a Class III medical device under the MDA that has received premarket approval. *See* FDA, LCS(R) Total Knee System (P830055), Premarket Approval Database (July 26, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P830055; *see also Ali v. Allergan USA, Inc.*, 2012 WL 3692396, at *1-2 (E.D. Va. Aug. 23, 2012) (taking judicial notice of the federal regulations applicable to the medical device at issue).

The Supremacy Clause of the Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Under this principle, Congress has the power to pre-empt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) and *Gibbons v. Ogden*, 22 U.S. (9 Wheat.), 210-11 (1824)).

Using its preemption authority, in 1976, Congress passed the MDA, 21 U.S.C. § 360c *et. seq.*, which amended the Federal Food Drug and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et. seq.*, in part, to address the "inability of the common-law tort system to manage the risks associated with dangerous [medical] devices." *Riegel*, 552 U.S. at 315-16 (citations omitted). The MDA established three classes of medical devices, with Class III devices subjected to "the highest level of federal oversight." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012). Specifically, before a manufacturer can place a new Class III device on the market, it must apply for FDA approval and satisfy the Agency's "rigorous" premarket approval ("PMA") process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Once a device manufacturer receives PMA, "the MDA forbid[] the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

To enforce the MDA's goal of uniform regulation, § 360k(a) of the MDA provides that:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Analyzing the preemptive effect of § 360k(a), the Supreme Court in *Riegel* addressed whether state common-law actions against Class III device manufacturers for alleged design flaws impose requirements "different from, or in addition to" the requirements imposed by the FDA and federal law. 552 U.S. at 324-25. The Supreme Court held that the term "requirements" as used in § 360k(a) includes common-law duties, because "common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation." *Id.* at 324 (internal quotations and citations omitted). Therefore, the Court concluded that state common-law actions "are preempted under the MDA . . . to the extent that they are 'different from, or in addition to' the requirements imposed by federal law;" however, the Court preserved common-law claims that run "parallel" to federal requirements. *Id.* at 330 (citing *Lohr*, 518 U.S. at 495). As the Fourth Circuit explained following the *Riegel* decision, § 360k(a) preempts claims "that a Class III device violated state tort law *notwithstanding compliance* with the relevant federal requirements" but preserves claims "premised on a *violation* of FDA regulations." *Burrell v. Bayer Corp.*, 918 F.3d 372, 377 (4th Cir. 2019) (emphasis supplied) (internal quotations and citations omitted). Thus, § 360k(a) permits claims premised on a product's failure to conform to the FDA's requirements.

In addition to the MDA's express preemption of different or additional state-law obligations, the FDCA has an implied preemptive effect that state-law claims must also survive. Specifically, § 337(a) of the FDCA provides that, with some exceptions not applicable to this matter, "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and

in the name of the United States." 21 U.S.C. § 337(a). Section 337(a) impliedly preempts private enforcement of the FDCA where "the existence of [the MDA and FDCA] is a critical element" of a plaintiff's claims. *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 347-50, 353 (2001) (reasoning that "the relationship between a federal agency and the entity it regulates is inherently federal in character" and requires that the FDA have "flexibility" in choosing how to enforce suspected non-compliance).

Between the express preemption of § 360k(a) and the implied preemption of § 337(a), plaintiffs are left with a narrow gap within which to plead state-law causes of action: on the one hand, a "plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a));" and, on the other hand, a "plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis supplied) (quotations and citations omitted). "[A] plaintiff must allege a violation of federal regulations with sufficient facts to render the alleged violation plausible under *Twombly* and *Iqbal*," presenting more than conclusory allegations. *Ali*, 2012 WL 3692396, at *6 (collecting cases). Ultimately, "the key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is . . . the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." *Bass v. Stryker Corp.*, 669 F.3d 501, 511-12 (5th Cir. 2012) (emphasis and citations omitted). Within this narrow gap provided by federal law, the Court will analyze the plausibility of Plaintiff's claims.

### A. Plaintiff Fails to State Plausible and Non-Preempted Claims in Counts I, III and VII.

The Court finds that Plaintiff fails to state plausible and non-preempted claims in Count I (negligence), Count III (implied warranty of merchantability) and Count VII (punitive damages), because the facts alleged, taken as true, fail to state a plausible claim under Virginia law and fail to plausibly allege violations of federal requirements applicable to the RPK implant, preempting all three claims under § 360k(a).

Under Virginia law, a plaintiff may recover for personal injuries caused by product defects under either a negligence theory or a cause of action for breach of an implied warranty of merchantability. *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1114 (4th Cir. 1988). "The essential elements of a negligence claim in Virginia . . . are (1) the identification of a legal duty of the defendant to the plaintiff; (2) a breach of that duty; and (3) injury to the plaintiff proximately caused by the breach." *Talley v. Danek Med., Inc.*, 179 F.3d 154, 157 (4th Cir. 1999) (citing *Locke v. Johns-Manville Corp.*, 275 S.E.2d 900, 904 (Va. 1981)). As to the first element, "Virginia law imposes a duty on manufacturers to exercise ordinary care in making their products reasonably safe." *Ali*, 2012 WL 3692396, at *7 (citing *Carney v. Sears, Roebuck & Co.*, 309 F.2d 300, 304 (4th Cir. 1962)). Such a duty also applies under a theory of warranty of merchantability. *Logan v. Montgomery Ward & Co.*, 219 S.E.2d 685, 687 (Va. 1975).

To establish breach under either a negligence or merchantability theory, "the plaintiff must show[:] (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands." *Id.* (citations omitted). "Products are 'unreasonably dangerous' if they are (1) defective in assembly or manufacture; (2) imprudently designed; or (3) not accompanied by adequate warnings about

their hazardous properties." *Austin v. Clark Equip. Co.*, 821 F. Supp. 1130, 1133 (W.D. Va. 1993) (citing *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1043 (4th Cir. 1983)).

Here, in support of Counts I and III, Plaintiff alleges, and the Court accepts as true, that DePuy manufactures, markets and distributes the RPK implant system. (Compl. ¶¶ 15-16.) DePuy advertised that the RPK implant allowed for more natural movement than traditional knee replacements and involved less wear on the implant's parts. (Compl. ¶ 19.) DePuy also marketed itself as a "global leader[] in hip, knee and shoulder replacement, [and] as the largest provider of orthopaedic and neurological solutions in the world." (Compl. ¶ 21.) Before 2012, DePuy became aware that its RPK implants tended to fail prematurely, causing recipients extreme pain and damage to bone and tissue. (Compl. ¶ 22.) Although an unidentified party advertised that DePuy's RPK implant could last approximately fifteen years, many reports showed considerable numbers of implant failures after only one or two years. (Compl. ¶ 24.) In the last several years, DePuy has issued multiple recalls for components of its knee replacement systems. (Compl. ¶ 26.)

In September 2012, Plaintiff received a RPK implant in his left knee. (Compl. ¶ 27.) Approximately one year later, Plaintiff complained to his physician about unexplained and sudden pain in his left knee, though his physician noted no evidence of loosening in his RPK implant at that time. (Compl. ¶ 29.) After four years of undergoing unsuccessful conservative treatment, in 2017, Plaintiff's new orthopedic doctor observed a potential failure of Plaintiff's RPK implant. (Compl. ¶¶ 30-35.) Plaintiff's orthopedist advised that Plaintiff's pain, swelling and other issues could be the result of loosening in his implant. (Compl. ¶ 36.) After receiving unsuccessful conservative treatment, on August 29, 2017, Plaintiff underwent a total knee revision surgery, during which Plaintiff's surgeon noted swelling, effusion and an infection in

Plaintiff's knee, with loosening of the femoral and tibial components of Plaintiff's implant. (Compl. ¶¶ 37-39.)

None of the facts alleged by Plaintiff support a plausible right to relief under either a negligence or implied warranty of merchantability theory. Although Plaintiff concludes that DePuy breached its duty of care and warranty that the RPK implant was fit for its ordinary use, (Compl. ¶¶ 46-51, 62), Plaintiff does not allege facts specifying a plausible defect in the implants' manufacture or design, or in the warnings given with each implant. Instead, Plaintiff merely states that DePuy knew that some of its implant systems did not last as long as advertised, referring only generally to "many reports" warning of the implant systems' truncated durability, and failing to specify whether the reports referred to a defect that plausibly caused Plaintiff's injuries. (Compl. ¶¶ 22, 24.) And, although Plaintiff alleges that his knee revision surgeon noted loosening of the femoral and tibial components of his RPK implant, (Compl. ¶ 39), Plaintiff does not allege any connection between that loosening and a defect in the design or manufacture of the implant, rendering a defect in the manufacture or design of the implant merely conceivable, not plausible, *see Twombly*, 550 U.S. at 570 (stating that plaintiffs must "nudge[] their claims across the line from conceivable to plausible"); *Fields v. Jobar Int'l, Inc.*, 2014 WL 1513289, at *3 (E.D. Va. Apr. 16, 2014) ("It is impossible for this Court to determine whether or not Plaintiff states a plausible claim for negligent design without some disclosure in the pleading of the alleged defect or deficiency . . . ."); *Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013) ("A bare allegation of a 'defect' is no more than a legal conclusion." (collecting cases)).

Plaintiff's failure to specify a defect in the design or manufacture of his RPK implant, or in the warnings provided with the implant, likewise fails to rescue Counts I and III from

preemption. Courts considering the plausibility of common-law claims after the *Riegel* decision have generally required plaintiffs to identify specifically what went wrong in the manufacturing, warning or design process and the relevant FDA standards allegedly violated by that defect. *See, e.g.*, *Bass*, 669 F.3d at 510 (noting that a plaintiff meets the plausibility standard for medical device claims when the plaintiff "specifies with particularity what went wrong in the manufacturing process[, by way of example,] and cites the relevant FDA . . . standards . . . allegedly violated" (internal quotations and citations omitted)); *id.* at 517 (holding that "an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty" (emphasis supplied)); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) ("[The] plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue." (internal quotations and citations omitted)). Plaintiff fails to point to any FDA regulation applicable to the RPK implant, let alone a regulation violated by DePuy. (*See* Compl. ¶¶ 46-48 (stating only generally that DePuy breached a duty to comply with applicable federal, state and local requirements but mentioning no specific violations of those requirements).) Plaintiff likewise fails to connect his allegation that DePuy has recalled several components in its knee replacement systems — presumably because they failed to meet FDA requirements — with the loosening at issue in his implant. (*See* Compl. ¶ 26 (alleging that DePuy has issued recalls for several components in DePuy's knee replacement systems, without specifying the components or the systems covered by those recalls)); *see also Ali*, 2012 WL 3692396, at *12 (dismissing negligence and implied warranty claims, in part, because the plaintiffs failed to allege that the nine medical device models recalled by Allergan included the model that caused their alleged injuries). And, although Plaintiff

alleges that DePuy knew of problems with its knee implant systems and failed to disclose or intentionally concealed that information, which could plausibly sustain a parallel claim, Plaintiff fails to allege facts showing that DePuy possessed information concerning the defect that plausibly injured *him*; thus, even if DePuy violated federal regulations by failing to disclose problems with the RPK implant, § 337(a) impliedly preempts Plaintiff's failure-to-warn claim, because Plaintiff has alleged only general violations of federal requirements and not violations that caused his injuries. *Compare Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 738-39, 742, 747 (D. Md. 2015) (finding failure-to-warn claim plausible where: (1) the plaintiffs alleged that the defendant knew about and failed to properly study the potential danger of metal poisoning from its medical device, which was the same poisoning about which the plaintiffs complained; and, (2) the plaintiffs identified ongoing federal requirements applicable to the medical device in question that the defendant allegedly violated), (*with* Compl. ¶¶ 22, 89 (alleging that DePuy knew about problems in its knee replacement systems before 2012, including loosening of parts in the RPK implant, and concealed that information, but failing to allege facts to support an inference that DePuy knew about the defect, if any, that caused Plaintiff's injuries).)

If anything, Plaintiff's allegations support an inference that DePuy's *compliance* with FDA regulations resulted in a defective implant. Specifically, because Plaintiff fails to allege a violation of the PMA requirements applicable to the RPK implant, Plaintiff's allegations plausibly suggest that the RPK implant, though designed, manufactured and distributed under PMA guidelines, caused his alleged injuries. But such a theory of liability, if proven, would impose different and additional requirements on DePuy — precisely the outcome that Congress wished to avoid in enacting the MDA. *See Walker*, 670 F.3d at 580 (noting that "[a] common

law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is . . . expressly preempted by the MDA as interpreted by *Riegel*.'" (citing *Riegel*, 552 U.S. at 324-25)). Accordingly, the Court recommends that Counts I and III be dismissed for failure to state a plausible and non-preempted claim. Because Plaintiff's claim for punitive damages in Count VII relies on the same conduct pled in support of Count I, but to a higher degree of culpability, Count VII should also be dismissed.[2]

**B. Plaintiff Fails to State a Plausible and Non-Preempted Claim in Count II.**

The Court finds that Plaintiff fails to allege a plausible and non-preempted claim in Count II, because Plaintiff has not alleged facts sufficient to state a plausible right to relief under Virginia law and has likewise failed to allege warranties made by DePuy that violated or exceeded the scope of federal regulations applicable to the RPK implant.

The Virginia UCC provides that in certain circumstances a seller of goods creates express warranties, the breach of which may be enforced by the buyer. Va. Code § 8.2-313. For example, when a seller makes "[a]ny affirmation of fact or promise . . . to the buyer which relates to the goods and becomes part of the basis of the bargain" the seller "creates an express warranty that the goods shall conform to the affirmation or promise." Va. Code § 8.2-313(1)(a). "Any

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[2] Although DePuy correctly notes that Plaintiff cannot sustain a cause of action for punitive damages, because Virginia does not recognize a standalone action for such damages, *Augustin v. SecTek, Inc.*, 807 F. Supp. 2d 519, 526 (E.D. Va. 2011); (Def.'s Mem. at 17), the Court interprets Count VII as a claim for willful and wanton negligence, which Plaintiff may sustain as a standalone action, *see Fravel v. Ford Motor Co.*, 973 F. Supp. 2d 651, 654-55 (W.D. Va. 2013) (explaining that Rule 8(f) requires courts to construe a claim by its substance, not the label provided). In any case, because Plaintiff's allegations of willful and wanton conduct rely on the facts alleged in support of ordinary and gross negligence in Count I, the Court recommends dismissal of Count VII for the same reasons provided in the Court's analysis of Count I.

description of the goods which is made part of the basis of the bargain [also] creates an express warranty that the goods shall conform to the description." Va. Code § 8.2-313(1)(b). And the Virginia UCC details that "[a]ny sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model." Va. Code § 8.2-313(1)(c).

To establish an express warranty claim, the buyer need not plead actual reliance. *See Daughtrey v. Ashe*, 413 S.E.2d 336, 338-39 (Va. 1992) (noting that "'affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown . . . .'" (quoting Va. Code § 8.2-313 cmt. 3)); *Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 105 (4th Cir. 1997) (explaining that because express warranties form the basis of the bargain, "[i]t is unnecessary that the buyer actually rely upon it"). Neither must a plaintiff point to particular words, for "'[t]echnical specifications, blueprints and the like can afford more exact description than mere language . . . .'" *Kraft Foods N. Am., Inc. v. Banner Eng'g Sales, Inc.*, 446 F. Supp. 2d 551, 570-71 (E.D. Va. 2006) (quoting Va. Code § 8.2-313 cmt. 5)). "An affirmation of fact is presumed to be part of the bargain [between the parties], and any fact that would remove such affirmation out of the agreement 'requires clear affirmative proof.'" *Yates v. Pitman Mfg., Inc.*, 514 S.E.2d 605, 606 (Va. 1999) (quoting *Daughtrey*, 413 S.E.2d at 339 (internal quotations omitted)). However, "[e]xpress warranties are not presumed and will not be inferred from ambiguous, inconclusive, or general discussions." *Whitehorse Marine, Inc. v. Great Lakes Dredge & Dock Co.*, 751 F. Supp. 106, 108 (E.D. Va. 1990) (internal citations omitted).

In support of his express warranty claim, Plaintiff alleges, and the Court accepts as true, that DePuy advertised that the RPK implant provided more natural movement than traditional

knee replacements, reduced internal wear and tear on the implant's parts and addressed a patient's need to rotate on his or her knee. (Compl. ¶ 19.) DePuy also marketed itself as a global leader in hip, knee and shoulder replacements and the largest provider of orthopedic and neurological solutions. (Compl. ¶ 21.) An unidentified party, presumably DePuy, advertised that DePuy's knee implant systems lasted approximately fifteen years, though "many reports" showed that a considerable number of DePuy systems failed after only one or two years. (Compl. ¶ 24.) After receiving a RPK implant in September 2012, Plaintiff started to experience continued pain that proved unresponsive to conservative treatments, eventually requiring knee revision surgery in August 2017. (Compl. ¶¶ 27-39.) At the time of his revision surgery, Plaintiff's surgeon noted that the femoral and tibial components of Plaintiff's RPK implant had loosened. (Compl. ¶ 39.)

Plaintiff's facts fail to state a plausible right to relief under an express warranty theory. Although Plaintiff alleges that DePuy's "advertisement, labeling, marketing, and promotion" of the RPK implant as "safe, effective, fit, and proper for its intended use" constituted an express warranty, (Compl. ¶ 53), Plaintiff points to no specific warranties that plausibly formed the basis of his decision to purchase the RPK implant, *see Hubbard v. Dresser, Inc.*, 624 S.E.2d 1, 4 (Va. 2006) (holding that an express warranty claim that "merely parrot[s] the language of § 8.2-313, which sets forth several *legal* bases for the creation of express warranties, and amount[s] to no more than a legal conclusion," proves insufficient to establish a right to relief (emphasis supplied) (internal quotations and citations omitted)). Indeed, although Plaintiff alleges that DePuy advertised that the RPK implant reduced internal wear and tear and permitted more natural movement, (Compl. ¶¶ 19, 24), such allegations fail to establish anything more than DePuy's opinion regarding the quality of its product, *see* Va. Code § 8.2-313(2) (providing that

"an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty"); *Bayliner Marine Corp. v. Crow*, 509 S.E.2d 499, 502 (Va. 1999) (holding that statement in sales brochure that the boat sold to the plaintiff "delivers the kind of performance you need to get to the prime offshore fishing grounds" merely "expressed the manufacturer's opinion concerning the quality of the boat's performance" and did not create an express warranty (internal quotations omitted)). And, although Plaintiff alleges that an unidentified party, presumably DePuy, marketed DePuy's knee implant systems as lasting approximately fifteen years, Plaintiff fails to point to any words or language that established a guarantee of durability by DePuy as to the RPK implant system that Plaintiff received. (*Compare* Compl. ¶ 24 (alleging that "[DePuy's] Knee Replacement Systems are marketed to last approximately 15 years," without specifying which systems were marketed, who marketed them or the exact warranty of durability for Plaintiff's implant), *with Daughtrey*, 413 S.E.2d at 338 (holding that jeweler created express warranty when he described the diamonds that he sold to the plaintiff as "H color and v.v.s. quality," which represented a specific quality of diamond (internal quotations omitted)).

Plaintiff's facts likewise fail to establish a claim that plausibly survives preemption. To avoid preemption, "'[a] plaintiff's breach of express warranty claim must 'identify representations of the manufacturer which exceed the scope of the FDA-approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer.'" *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285 (E.D.N.Y. 2009) (quoting *Lake v. Kardjian*, 22 Misc. 3d 960, 963 (N.Y. Sup. Ct. 2008)).

Here, Plaintiff points to no specific representations by DePuy regarding the RPK implants that exceeded the scope of the statements that the FDA permitted DePuy to make.

Although Plaintiff alleges that DePuy made various representations regarding the durability of the RPK implant and its implant systems generally, (Compl. ¶¶ 19, 24), Plaintiff fails to identify the FDA regulations that DePuy violated or exceeded in making those representations. In fact, Plaintiff's allegations directly attack DePuy's representations about the safety and effectiveness of the FDA-approved RPK implant, (Compl. ¶ 53), which goes to the heart of the MDA's preemptive scope. *See Ali*, 2012 WL 3692396, at *16 (holding that breach of express warranty claims that "ultimately challenge the FDA's safety and effectiveness determination" fall within the MDA's preemptive scope, because the FDA determines that a device qualifies as a safe and effective through the PMA process).

Moreover, the Court finds unpersuasive Plaintiff's argument that DePuy's alleged representations appeared only in non-FDA approved promotional and advertising materials and therefore related to matters beyond the scope of FDA regulations and the MDA. (Pl.'s Mem. at 5.) Plaintiff's facts do not allege in what documents DePuy made the representations at issue, rendering Plaintiff's argument conceivable, but not plausible. The only representation that could potentially fall beyond the scope of FDA-approved messaging would be the advertisement, presumably issued by DePuy, that DePuy's knee replacement systems last approximately fifteen years, (Compl. ¶ 24); however, Plaintiff fails to allege with sufficient specificity the materials in which DePuy made this representation, whether the FDA sanctioned such a representation and whether the representation applied to the RPK implant that Plaintiff received. Accordingly, the Court recommends that Count II of Plaintiff's Complaint be dismissed for failure to state a plausible and non-preempted claim.

### C. Plaintiff Fails to State a Plausible and Non-Preempted Claim in Count IV.

Plaintiff likewise fails to state a plausible and non-preempted claim in Count IV (implied warranty of fitness for a particular purpose), because Plaintiff's facts fail to state a plausible right to relief under Virginia law, and because the FDA declared the RPK implant safe for the use that Plaintiff intended, precluding his fitness-for-purpose claim.

Under Virginia's UCC, "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Va. Code § 8.2-315. To recover for breach of the implied warranty of fitness for a particular purpose, a plaintiff must prove that:

> (1) the seller had reason to know of the particular purpose for which the buyer required the goods, (2) the seller had reason to know the buyer was relying on the seller's skill or judgment to furnish appropriate goods, and (3) the buyer in fact relied upon the seller's skill or judgment.

*Medcom, Inc. v. C. Arthur Weaver Co.*, 348 S.E.2d 243, 246 (Va. 1986). Further, "[a] claim for breach of warranty for a particular purpose requires a plaintiff to allege that the product failed to serve a purpose other than its ordinary purpose and peculiar and unique to the plaintiff." *Whitaker v. Hyundai Motor Co.*, 2017 WL 3197243, at *2 (W.D. Va. July 27, 2017) (internal quotations and citations omitted); *see also* Va. Code § 8.2-315 cmt. 2 ("A 'particular purpose' . . . envisages a specific use by the buyer which is peculiar to the nature of his business whereas ordinary purposes for which goods are used . . . go to uses which are customarily made of the goods in question.").

In support of Count IV, the Court accepts as true that DePuy manufactured the RPK implant for the purpose of replacing natural knee joints with an artificial system that mirrored the movement of a natural knee and reduced internal wear and tear. (Compl. ¶¶ 16-18.) After

receiving a RPK implant in September 2012, Plaintiff started to experience continued pain that proved unresponsive to conservative treatments, eventually requiring knee revision surgery in August 2017. (Compl. ¶¶ 27-39.) At the time of his revision surgery, Plaintiff's surgeon noted that the femoral and tibial components of Plaintiff's RPK implant had loosened. (Compl. ¶ 39.)

Plaintiff's facts fail to allege a plausible right to relief under a fitness-for-purpose theory. Nowhere in his Complaint does Plaintiff allege sufficient facts to support an inference that DePuy had reason to know that Plaintiff intended to use the RPK implant for a purpose "peculiar to the nature of his business" and not for "uses which are customarily made of [RPK implants]." Va. Code § 8.2-315 cmt. 2. In fact, Plaintiff alleges that, "[a]t all relevant times, [he] used the [RPK implant] for the purpose and in the manner intended by [DePuy]," which, taken as true, draws the opposite inference to the one needed to sustain Count IV at this stage in the proceedings. (Compl. ¶ 70.)

Indeed, Plaintiff could not allege that DePuy breached the implied warranty of fitness for a particular purpose, because the PMA process declares devices fit for a specific purpose and any allegation that a device is not fit for that purpose would run against the FDA's findings to the contrary, bringing such a claim within the preemptive scope of the MDA. *See Williams*, 123 F. Supp. 3d at 742 (rejecting fitness-for-purpose claim, because "the FDA, through the PMA process, expressly defines the scope of a device's 'intended use'" (quoting 21 U.S.C. § 360e(c)(2)(A)(iv))); *Hesik v. Boston Sci. Corp.*, 2014 WL 5644699, at *8 (D.S.C. Nov. 4, 2014) (denying fitness-for-purpose claim, because "the FDA has already provided federal requirements relating to the design and manufacture of the [device in question] through the PMA process"); *Bishoff v. Medtronic, Inc.*, 2010 WL 4852650, at *3 (N.D. W. Va. Nov. 22, 2010) ("The FDA's approval of Medtronic's device through the PMA process belies [the plaintiff's]

claim and preempts any claim that the device was unfit for its intended purpose." (citations omitted)). Plaintiff does not allege that he used the RPK implant for any purpose other than those purposes approved by the FDA. Accordingly, Plaintiff fails to state a plausible and non-preempted claim in Count IV.

## V. CONCLUSION

For the reasons set forth above, the Court recommends that DePuy's Motion to Dismiss (ECF No. 18) be GRANTED, that Counts I, II, III and VII of Plaintiff's Complaint (ECF No. 1) be DISMISSED WITHOUT PREJUDICE and that Counts IV, V and VI be DISMISSED WITH PREJUDICE.[3]

Let the Clerk forward a copy of this Report and Recommendation to Senior United States District Judge Robert E. Payne and all counsel of record.

## NOTICE TO PARTIES

**Failure to file written objections to the proposed findings, conclusions and recommendations of the Magistrate Judge contained in the foregoing report within fourteen (14) days after being served with a copy of this report may result in the waiver of any right to a de novo review of the determinations contained in the report and such failure**

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[3] Dismissal with prejudice constitutes the appropriate action as to Counts IV, V and VI, because any amendments to Plaintiff's facts would be futile, as no set of facts could cure the implausibilities and legal deficiencies noted by this Court. *See Conner v. Nucor Corp.*, 2015 WL 5785510, at *5 (D.S.C. Sept. 30, 2015) (finding dismissal with prejudice appropriate where "[a]mendment of the factual assertions in the Complaint would not cure the legal deficiency at issue and would be futile" (quotations and citations omitted)). Specifically, because the FDA approved the RPK implant for Plaintiff's intended purpose (i.e., as a knee replacement), Plaintiff cannot argue that DePuy breached a warranty that the implant would be fit for a particular purpose without imposing additional or different state-law requirements. As for Counts V and VI, Virginia does not recognize a strict liability scheme in products liability cases, precluding any cognizable action for strict liability based on Plaintiff's facts. *Lust*, 792 F.2d at 439.

**shall bar you from attacking on appeal the findings and conclusions accepted and adopted by the District Judge except upon grounds of plain error.**

/s/
David J. Novak
United States Magistrate Judge

Richmond, Virginia
Date: August 6, 2019